



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	C.A. No. 21-1015 (GBW)
)	
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	REDACTED - PUBLIC VERSION
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN
AUSTRALIA’S OPENING BRIEF IN SUPPORT OF THEIR MOTIONS TO EXCLUDE
CERTAIN OPINIONS AND TESTIMONY OF
PLAINTIFF/COUNTER-DEFENDANTS’ EXPERTS**

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'361 Patent	U.S. Patent No. 9,708,361
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
<i>Bold and Italic</i>	Emphasis added unless indicated otherwise
Ex. ____	Exhibit ____ ¹
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PTO	United States Patent and Trademark Office
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827

¹ Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.

I. INTRODUCTION

Sarepta and UWA respectfully request that the Court exclude:

- (1) the opinions and testimony of Scott E. Kamholz, Esq. relating to inequitable conduct;
- (2) the opinions and testimony of Dr. Christine C. Esau relating to noninfringement of the Wilton Patents;
- (3) the opinions and testimony of Dr. Christine C. Esau and Dr. Michelle L. Hastings relating to willful infringement and the opinions and testimony of Dr. Matthew J. A. Wood relating to conception (collectively, the “state of mind” opinions and testimony); and
- (4) the opinions and testimony of Dr. Nathan W. Luedtke relating to infringement of the ’322 Patent under the doctrine of equivalents.

II. LEGAL STANDARD FOR ADMISSIBILITY OF EXPERT TESTIMONY

An expert may only proffer opinions if “the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702(a). As emphasized in the recent revision to Rule 702 (effective Dec. 1, 2023), the proponent of an expert’s testimony bears the burden to “demonstrate[] to the court that it is more likely than not” that this expertise is helpful, *id.*, and that the expert’s “testimony is based on sufficient facts or data” and “is the product of reliable principles and methods,” and that their “opinion reflects a reliable application of the principles and methods to the facts of the case,” *id.* at 702(b)-(d).

The admissibility of expert testimony follows the law of the regional circuit. *See Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1390-91 (Fed. Cir. 2003). In the Third Circuit, the admissibility determination focuses on the “trilogy of restrictions on expert testimony: qualification, reliability and fit.” *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003). Qualification requires that “the witness possess specialized expertise.” *Id.* To be reliable,

“the expert’s opinion must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’” *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993)). To be fit, “the expert’s testimony must be relevant for the purposes of the case and must assist the trier of fact.” *Id.*

III. NATURE AND STAGE OF THE PROCEEDINGS

NS initiated this litigation on July 13, 2021, asserting that Sarepta infringes the claims of U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; and 10,683,322. Sarepta and UWA counter-sued on U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827. Fact and expert discovery are closed. Trial is scheduled for seven days, starting on May 13, 2024. D.I. 143, ¶21.

IV. MOTION #1: EXCLUSION OF DR. KAMHOLZ’S OPINIONS AND TESTIMONY

A. Introduction

NS’s “patent law expert,” Dr. Kamholz,² intends to offer various opinions in support of NS’s defense that the Wilton Patents are unenforceable for inequitable conduct. But Dr. Kamholz’s opinions are rife with conjecture as to the knowledge, state of mind, intent, and beliefs of two of the named inventors on the Wilton Patents, Drs. Wilton and Fletcher, and an attorney who prosecuted the ’851 Patent, Ms. Mandragouras. In rendering his opinions, Dr. Kamholz speculates as to what those individuals “knew or should have known,” which is an improper legal standard that has no place in analyzing inequitable conduct.

Dr. Kamholz also offers “expert” opinions on technical issues involving laboratory notebooks, a scientific publication from the Wilton laboratory, and data in the Wilton Patents—

² Dr. Kamholz has M.D. and Ph.D. degrees [REDACTED]
[REDACTED]. Ex. 33, 9:19-10:6; 11:15-23; 15:13-15.

despite acknowledging that he is not a technical expert. Further, he improperly speculates as to what the patent examiner would have done during prosecution. Because Dr. Kamholz's opinions do not comport with the requirements of *Daubert* and are contrary to established precedent in this district, he should be precluded from offering those opinions at trial. Indeed, because his expert reports contain so many deficiencies, he should be precluded from providing any testimony at all.

B. Argument

1. Patent Law Experts Are Generally Disfavored in This District

“[T]his [c]ourt has a strong and consistent view with respect to the admittance of the testimony of ‘patent law experts.’” *Shire Viropharma Inc. v. CSL Behring LLC*, C.A. No. 17-414-MSG, 2021 WL 1227097, *16 (D. Del. Mar. 31, 2021) (quoting *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, C.A. No. 11-515-LPS-CJB, 2015 WL 12815314, at *3 (D. Del. Nov. 20, 2015)). Although the court has “at times” permitted testimony “clearly related to the ins and outs of internal PTO practices and procedures[,] [b]eyond that narrow topic . . . courts have ***generally excluded patent law expert testimony*** relating to inequitable conduct largely because such testimony frequently amounts to the proffering of impermissible legal opinions.” *Id.* (internal citation omitted); *see also AstraZeneca UK Ltd. v. Watson Labs., Inc. (NV)*, C.A. No. 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012) (“[T]he judges in this District have a well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances.”) (citing cases). As set forth below, Dr. Kamholz's proffered testimony is illustrative of all of the reasons that patent law experts are disfavored, and the Court should not depart from the standard practice of excluding such testimony here.

2. Dr. Kamholz’s Opinions Applying the Wrong Legal Standard Should Be Excluded

Dr. Kamholz repeatedly opined on what, in his view, Dr. Wilton, Dr. Fletcher, and Ms. Mandragouras “knew or should have known”—a phrase reiterated in his expert reports 20 times. *See* Ex. 24, ¶¶1, 32-33, 36-37, 55, 73, 78-79; Ex. 26, ¶¶2, 12, 17, 21, 27, 29-30. At his deposition, Dr. Kamholz [REDACTED]

[REDACTED]

[REDACTED]” Ex. 33, 49:3-7. [REDACTED]

[REDACTED]

[REDACTED]

See, e.g., id., 48:11-13 (“[REDACTED]

[REDACTED]”); *see also id.*, 49:8-13; 50:21-24; 79:10-13, 79:18-21, 80:1-4.

Dr. Kamholz’s reliance on a “knew or should have known” standard is fatal to the admissibility of his opinions, as that is not the legal standard for intent. The en banc Federal Circuit held in *Therasense* that proof of intent requires “clear and convincing evidence that the applicant **knew** of the reference, **knew** that it was material, and made a **deliberate decision** to withhold it.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). *Therasense* expressly rejected the prior “should have known” standard incorporated in Dr. Kamholz’s opinions: “[a] finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard **does not satisfy**” the requirement to prove that “the patentee acted with the specific intent to deceive the PTO.” *Id.*

Thus, Dr. Kamholz’s opinions that the inventors and Ms. Mandragouras “knew or should have known” that statements in the inventorship declaration or data in the Wilton Patents were false or misleading cannot help the factfinder, since these opinions apply an incorrect legal

[REDACTED]

standard. [REDACTED]

[REDACTED]. Ex. 33, 48:18-23; 49:3-7.

Accordingly, those opinions would be unhelpful and confusing to the factfinder and should be excluded under Fed. R. Evid. 702. *Sprint Commc'ns Co. L.P. v. Cox Commc'ns Inc.*, 302 F. Supp. 3d 597, 619 (D. Del. 2017) (excluding expert testimony under *Daubert* that is “contrary to the law and [], therefore, unhelpful and likely to confuse a jury”).

3. Dr. Kamholz’s Opinions Concerning State of Mind Should Be Excluded

Courts generally prohibit expert opinion concerning a party’s intent, motive, or state of mind, or evidence by which such state of mind may be inferred. *W.R. Grace & Co. – Conn. v. Elysium Health, Inc.*, C.A. No. 20-1098-GBW-JLH, D.I. 291 at *7-8 (D. Del. Aug. 10, 2023) (Ex. 58); *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 497 (D. Del. 2019) (“Expert testimony as to intent, motive, or state of mind offers no more than the drawing of an inference from the facts of the case ... and permitting expert testimony on this subject would be merely substituting the expert’s judgment for the [fact finder’s] and would not be helpful to the [fact finder].”); *W.L. Gore*, 2015 WL 12815314, at *5 (holding such testimony is infused “with speculation as to what may have been in another’s mind.”). *See infra* § VI.

Dr. Kamholz’s opinions regarding the veracity of the inventors’ beliefs, what they subjectively regarded as their invention, and what they and Ms. Mandragouras “knew or should have known” are not the proper subject of expert testimony (and reflect no more than raw speculation). [REDACTED]

[REDACTED]. *See* Ex. 24, ¶¶31-33 ([REDACTED])

[REDACTED]), 36-37 ([REDACTED])

[REDACTED]

[REDACTED]

[REDACTED]”); *see also id.*, ¶¶55, 73-74, 78-79 ([REDACTED]

[REDACTED]”); Ex. 26, ¶¶2 ([REDACTED]

[REDACTED]), 6-8, 12 ([REDACTED]

[REDACTED]”). As in *W.L. Gore*, the Court should not permit Dr. Kamholz to speculate as to “what may have been in another’s mind,” 2015 WL 12815314, at *5, and should exclude his opinions regarding purported knowledge, state of mind, intent, or beliefs.

4. Dr. Kamholz’s Opinions Regarding What the Patent Examiner Would Have Done Should Be Excluded

Expert testimony regarding what a patent examiner would have done if presented with information is also impermissible. *W.L. Gore*, 2015 WL 12815314, at *4-5; *Purewick Corp. v. Sage Prods., LLC*, C.A. No. 19-1508 (MN), 2021 WL 2593338, *1-2 (D. Del. Jun. 24, 2021).

Dr. Kamholz improperly opines as to what the Examiner would have done had she been aware of information Dr. Kamholz contends was withheld or allegedly misrepresented. Ex. 24, ¶¶38 ([REDACTED]

[REDACTED]”), 35 [REDACTED]; Ex. 26, ¶23 ([REDACTED]

[REDACTED]

[REDACTED]”). Such testimony is impermissible and should be excluded. *W.L. Gore*, 2015 WL 12815314, at *5 (excluding opinions “on what would have happened in the [PTO] if certain information that was not disclosed ... had been disclosed” because it “is infused to too great a degree with what sounds like legal opinion, or with speculation as to what may have been in another’s mind”); *Purewick*, 2021 WL 2593338, *1–2 (explaining that “testimony of patent law experts that . . . opine on how the Patent Office would have acted in certain circumstances ha[s] regularly been excluded” and excluding testimony as to why “the examiner [] did or did not do

[REDACTED]

something”); *cf. ART+COM Innovationpool GmbH v. Google Inc.*, 155 F. Supp. 3d 489, 509-10 (D. Del. 2016) (permitting technical expert to testify on the accuracy of a declaration submitted to the PTO that was the basis of an inequitable conduct challenge, because such testimony is “within his field of expertise” and “helpful” to the determination of inequitable conduct).

5. Dr. Kamholz’s Opinions on Technical Matters Should Be Excluded

Dr. Kamholz holds himself out as a patent law expert. [REDACTED]

[REDACTED] Ex. 33, 15:13-16:5, 31:11-20. [REDACTED]

[REDACTED]. *See, e.g.*, Ex. 24, ¶34 (“[REDACTED]

[REDACTED]”); *see also id.*, ¶¶51-56, 58, 60-74, 76-78, 83; Ex. 25, ¶¶21, 23, 32.³ Although

Dr. Kamholz cites to Dr. Hastings’ expert reports in some paragraphs of his reports, [REDACTED]

[REDACTED] *See, e.g.*, Ex. 24, ¶62 (“[REDACTED]

[REDACTED]”).

Because Dr. Kamholz is not qualified to render technical opinions, his testimony regarding “but-for” materiality—which here is determined from the perspective of a POSA and therefore

³ Dr. Kamholz’s Responsive Report (Ex. 25) similarly provides opinions regarding what the Examiner would have done had certain technical information been disclosed during prosecution of NS’s patents. *Id.*, ¶¶19, 29. Those opinions should likewise be excluded because Dr. Kamholz is not a technical expert [REDACTED]. Ex. 33, 15:13-16:5, 31:11-20.

requires a technical understanding of the purportedly withheld information—should be excluded.⁴ See *Ojmar US, LLC v. Sec. People, Inc.*, Case No. 16-04948, 2018 WL 3008872, at *2-3 (N.D. Cal. Jun. 15, 2018) (precluding patent expert who was not a technical expert or a POSA from testifying regarding materiality because the “but-for” materiality inquiry required examination of the withheld references and the technical aspects of the field at issue); accord *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1361, 1362 (Fed. Cir. 2008) (“Unless a patent lawyer is also a qualified technical expert, his testimony on . . . technical issues is improper and thus inadmissible.”).

C. Conclusion

Sarepta respectfully requests that the Court preclude Dr. Kamholz from providing testimony (i) applying the incorrect “knew or should have known” standard; (ii) regarding knowledge, state of mind, intent, and beliefs of others; (iii) speculating as to what the patent examiner would have done during prosecution; and (iv) regarding “expert opinions” on technical matters. Because nearly all the opinions set forth Dr. Kamholz’s expert reports are plagued with the deficiencies set forth above, Sarepta further requests that the Court exclude Dr. Kamholz’s testimony in its entirety.

⁴ In *Persawvere, Inc. v. Milwaukee Elec. Tool Corp.*, C.A. No. 21-400-GBW, 2023 WL 8019085 (D. Del. Nov. 20, 2023), this Court permitted a patent expert to opine on “whether an objectively reasonable patent examiner would have considered certain information material in deciding whether to allow the application to issue as a patent.” *Id.* at *14. *Therasense* rejected the prior “reasonable patent examiner” standard in favor of the more stringent “but for” materiality standard, 649 F.3d at 1287-88, 1291, and the parties in *Persawvere* did not address whether testimony from a non-technical expert under the “but for” standard was appropriate. See C.A. No. 21-400-GWB, D.I. 138 at *4-10 (Ex. 59); D.I. 184 at *5-6 (Ex. 60); D.I. 165 at *2-4 (Ex. 61).

V. **MOTION #2: EXCLUSION OF DR. ESAU’S NON-INFRINGEMENT OPINION AND TESTIMONY**

The non-infringement opinion of NS’s expert Dr. Christine Esau should be excluded in its entirety. Dr. Esau bases her opinion on a claim construction of the Wilton Patents that is not only precluded by the Court’s *Markman* ruling, [REDACTED]. Indeed, [REDACTED]

When, as here, the court has rendered a claim construction ruling, an expert’s opinions on infringement must apply the construction of the claim terms given by the court. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010) (district court did not err in excluding expert testimony arguing for a limitation specifically rejected by the court); *see also CAO Lighting, Inc. v. Gen. Elec. Co.*, C.A. No. 20-681-GBW, 2023 WL 1930354, at *4-7 (D. Del. Jan. 30, 2023) (excluding expert opinion contrary to claim construction); *Minerva Surgical, Inc. v. Hologic, Inc.*, C.A. No. 18-217-JFB-SRF, 2021 WL 3048447, at *8-9 (D. Del. July 20, 2021) (striking technical expert’s infringement testimony because the expert applied a claim construction that the court had rejected).

As explained in Sarepta’s concurrently filed Motion for Summary Judgment of Infringement, Dr. Esau’s non-infringement opinions are premised on a claim construction that contradicts the Court’s *Markman* ruling [REDACTED]

[REDACTED]. The Court’s *Markman* ruling explained that the phrase “in which uracil bases are thymine bases” modifies the *entire* ASO, *including* the preceding base sequence limitation (selected from SEQ ID NO: 195). D.I. 248 at 28-29. In conflict with this ruling, Dr. Esau argues [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In other words, although the Court construed the term “in which uracil bases are thymine bases” to require thymine bases throughout the entire claimed ASO, which *must* include the portion of the ASO derived from SEQ ID NO: 195, Dr. Esau [REDACTED]

[REDACTED].

Further contributing to improper jury confusion, [REDACTED] thus violating the principle that “claims are construed the same way for both validity and infringement.” *See, e.g., TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017) (“Claim terms must be construed the same way for the purpose of determining invalidity and infringement.”). Unlike Dr. Esau, Dr. Hastings [REDACTED]

[REDACTED]

[REDACTED] Ex. 32, 157:11-158:15. [REDACTED]

[REDACTED]. Compare Ex. 22, ¶¶48, 101 with Ex. 31, 31:24-33:1 ([REDACTED]).

Dr. Esau’s non-infringement opinion—[REDACTED]

[REDACTED]—is thus contrary to the Court’s *Markman* ruling and should be excluded in its entirety.

VI. MOTION #3: EXCLUSION OF THE “STATE OF MIND” OPINIONS AND TESTIMONY OF NS’S EXPERTS

A. Drs. Esau and Hastings Improperly Speculate About Sarepta’s State of Mind in Offering Opinions on Willful Infringement

“Expert witnesses are not ‘permitted to testify . . . regarding [a party’s] intent, motive, or state of mind, or evidence by which such state of mind may be inferred.’” *AstraZeneca LP v. TAP Pharm. Prods., Inc.*, 444 F. Supp. 2d 278, 293 (D. Del. 2006) (quoting *Oxford Gene Tech. Ltd. v.*

[REDACTED]

Mergen Ltd., 345 F. Supp. 2d 431, 433 (D. Del. 2004)). Otherwise, “expert testimony on this subject would be merely substituting the expert’s judgment for the jury’s and would not be helpful to the jury.” *Zimmer Surgical*, 365 F. Supp. 3d at 497. Such testimony “goes beyond what is permissible by a technical expert” and invokes the Court’s gatekeeping role under *Daubert*. See *W.R. Grace*, C.A. No. 20-1098-GBW-JLH, D.I. 291, at *7-8 (Ex. 58).

Here, the Court should exclude the opinions of NS’s experts Drs. Esau and Hastings concerning Sarepta’s alleged willful infringement of the ’092, ’461, ’106, ’741, and ’217 Patents because both improperly speculate about Sarepta’s purported state of mind. See Ex. 20, §§ XI.D, XII.D; Ex. 23, § VIII. [REDACTED]

[REDACTED] See Ex. 20, §§ XI.D, XII.D. As illustrated below, her willfulness testimony [REDACTED]

[REDACTED]. Such testimony would not be helpful to the jury.

Dr. Esau improperly opines:

- [REDACTED]
- [REDACTED]
- [REDACTED]

NS’s expert Dr. Hastings similarly speculates about Sarepta’s purported state of mind,

[REDACTED]

[REDACTED] See Ex. 23, ¶¶84-85 (“[REDACTED]”); Ex. 32,

234:13-21. [REDACTED]

[REDACTED] But, as this Court explained, Dr. Hastings should not be permitted to “subsume the role of the fact-finder.” *See W.R. Grace*, C.A. No. 20-1098-GBW-JLH, D.I. 291, at *7-8 (Ex. 58).

Courts have consistently excluded speculative expert opinions like those of Drs. Esau and Hastings in the context of willful infringement. In *Zimmer Surgical*, Judge Andrews excluded expert testimony on whether a party’s reliance on the opinions of counsel was unreasonable because such “testimony as to intent, motive, or state of mind offers no more than the drawing of an inference from the facts of the case” and therefore “would not be helpful to the jury.” 365 F. Supp. 3d at 497; *see also Sonos, Inc. v. D & M Holdings Inc.*, 297 F. Supp. 3d 501, 520-22 (D. Del. 2017) (Bryson, J, sitting by designation) (precluding party from offering testimony on copying in the context of willful infringement, which merely “invok[es] the special imprimatur that accompanies [evidence] present[ed] by an expert”); *Fuma Int’l LLC v. R.J. Reynolds Vapor Co.*, Case No. 1:19-CV-260, 2021 WL 4820738, at *3 (M.D.N.C. Oct. 15, 2021) (expert’s willfulness opinions about “intent and motives” “will not be allowed at trial”); *Trading Techs. Int’l, Inc. v. IBG LLC*, Case No. 10 C 715, 2020 WL 12333010, at *2 (N.D. Ill. Oct. 21, 2020) (excluding expert opinions that a party’s conduct was “egregious, wanton, and demonstrates bad

⁵ Dr. Hasting’s speculation about Sarepta’s alleged state of mind lacks evidence. In contrast,

[REDACTED]

See Ex. 19, § VIII.

See, e.g., Ex. 32, 236:8-238:2, 241:21-243:4. See Ex. 31, 17:6-9 ([REDACTED]), 17:13-18:8 ([REDACTED]).

faith” because “[i]t is the role of the jury to decipher the evidence and make inferences from it about a party’s intent”).

“[I]t is not helpful to jurors for an expert to tell them what he thinks about an institution’s intent.” *Trading Techs.*, 2020 WL 12333010, at *2. The willfulness opinions of Drs. Esau and Hastings should therefore be excluded.

B. Dr. Wood Improperly Speculates as to the Inventor’s State of Mind in His Evaluation of Conception

NS’s expert Dr. Wood is not an inventor of the Wilton Patents. Nor did he consider contemporaneous documents or corroborating testimony from the inventors of the Wilton Patents.⁶ *See* Ex. 29, ¶2 (“I have reviewed only publicly available information”). Yet, he alleges that the inventors of the Wilton Patents did not conceive of the claimed inventions—i.e., he offered opinions concerning the *inventors’ state of mind*. *See* Ex. 29, §§ III.B, V.C; Ex. 30, §§ II.B-C. His speculation concerning what the inventors thought, believed, or intended when the Wilton Patents were filed in June 2005 should also be excluded.

For example, Dr. Wood repeatedly speculates that the inventors “had not formed *a definite and permanent idea*” about their invention. *See, e.g.*, Ex. 29, § V.C. He speculates that, as of June 2005, the inventors of the Wilton Patents had not “conceived, possessed, recognized, or appreciated” the claimed inventions. *See, e.g.*, Ex. 30, ¶35; *see also id.* ¶¶14, 17, 17 n.3, 19 (stating, e.g., that a POSA “would not have understood *the inventors to have discovered, possessed, recognized, or appreciated* any general properties of exon 53 skipping AONs”). Such testimony “goes beyond what is permissible by a technical witness,” and should be excluded. *See*

⁶ As explained elsewhere, Dr. Wood should not be permitted to participate in this litigation at all. Dr. Wood is subject to Sarepta’s pending motions to disqualify and to strike his expert reports, as well as Sarepta’s opposition to NS’s use of confidential Sarepta and UWA information. D.I. 298, 307, 385.

[REDACTED]

W.R. Grace, C.A. No. 20-1098-GBW-JLH, D.I. 291, at *7-8 (Ex. 58); *see also AstraZeneca UK Ltd.*, 2012 WL 6043266, at *2 (excluding expert opinions on “what the inventors . . . knew or intended”).

In response, NS may argue that Dr. Wood is opining from the perspective of “a POSA” rather than about what the inventors believed or appreciated. But NS and Dr. Wood cannot have it both ways. The pertinent portion of Dr. Wood’s Opening Expert Report does not mention the term “POSA” at all, and instead wrongly speculates as to the inventors’ state of mind. *See* Ex. 29, § V.C. By inserting the term “a POSA” in Dr. Wood’s Reply Expert Report, NS appears to be recasting Dr. Wood’s state of mind testimony on conception as an opinion on validity. [REDACTED]

[REDACTED]

[REDACTED] *See* D.I. 309, ¶3; D.I. 385; Ex. 35, 142:12-143:4
([REDACTED]
[REDACTED]). To the extent Dr. Wood’s opinions in his Reply Expert Report nevertheless concern conception, then they constitute improper “state of mind” testimony about what the inventors knew or believed as of June 2005, and therefore should be excluded.

VII. MOTION #4: EXCLUSION OF DR. LUEDTKE’S DOCTRINE OF EQUIVALENTS OPINIONS AND TESTIMONY

Sarepta respectfully moves to exclude Dr. Luedtke’s opinions and testimony concerning Sarepta’s purported infringement of U.S. Patent No. 10,683,322 (“the ’322 Patent”) (Ex. 10) under the doctrine of equivalents (“DOE”). Dr. Luedtke’s DOE analyses are legally erroneous and therefore unhelpful to a factfinder. Dr. Luedtke’s methodologies violate the “all elements rule” by *completely ignoring*—and thereby vitiating—a construed claim element [REDACTED]
[REDACTED] in assessing Sarepta’s purported infringement. His alternative “hypothetical

[REDACTED]

claim” analysis is legally wrong and cannot substitute for the required element-by-element consideration.

A. Introduction

Dr. Luedtke argues that Sarepta’s manufacture of golodirsen purportedly infringes claims 1-4 and 6-9 of NS’s ’322 Patent under the DOE. Claims 1 and 6 are the sole independent claims and both are directed to a solid-phase six-step method of making a phosphorodiamidate morpholino oligomer (“PMO”).⁷ Ex. 10, claims 1, 6. [REDACTED]

[REDACTED] Ex. 34, 32:6-33:1. During claim construction, this Court ordered that all six steps were required, but held that the order in which steps e) and f) were accomplished is irrelevant so long as they “*use[] Compound 4* having the *same chemical structure* as was previously defined.” D.I. 248 at 36 n.7, 37-38. [REDACTED]

[REDACTED]

[REDACTED] Ex. 28, ¶20; Ex. 34, 87:10-21. Nevertheless, he argues that Sarepta infringes under the DOE.

Dr. Luedtke purports to perform [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Dr. Luedtke explained that [REDACTED]

[REDACTED]

[REDACTED]” Ex. 34, 91:25-92:6. With “[REDACTED]” Dr. Luedtke

⁷ The ’322 Patent is the only Asserted Patent discussing solid-phase chemical manufacturing of PMOs. If Dr. Luedtke’s opinions are excluded, NS would be unable to prove infringement and both parties would likely no longer need to instruct the jury on this subject matter.

[REDACTED]

[REDACTED] *Id.*, 91:9-20; *see also id.*, 84:16-85:21 ([REDACTED]

[REDACTED]). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ex. 28, ¶11. Despite the Court's express determination in its construction that Compound 4 was necessary, Dr. Luedtke [REDACTED]

[REDACTED] (Ex. 34, 91:21-24, 86:2-12) and

a POSA [REDACTED]

[REDACTED] (*id.*, 103:3-20).

B. Legal Standard for Doctrine of Equivalents

A party relying on infringement under the doctrine of equivalents must show the accused product contains *each element* of the asserted claim or its equivalent. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). A party demonstrates equivalence of a claim

[REDACTED]

element by showing that the accused product performs “substantially the same function in substantially the same way to obtain the same result” (“FWR”) or that the accused product or process is insubstantially different from what is patented (“insubstantial differences”). *Mylan Inst. LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866 (Fed. Cir. 2017). A party’s reliance on “broad play as to effectively eliminate that element in its entirety” or merely conclusory expert testimony is insufficient for proving equivalence. *See Warner-Jenkinson*, 520 U.S. at 29.

C. Dr. Luedtke’s DOE Analyses Are Legally Erroneous and Should Be Excluded

1. Dr. Luedtke’s Analyses Violate the All Elements Rule

Dr. Luedtke’s DOE analyses fail to assess the construed ’322 Patent claims on an element-by-element basis. In *Minerva*, the court excluded expert DOE testimony based on a failure to opine on a claim element established by the court’s claim construction. *Minerva Surgical*, 2021 WL 3048447, at *6. There, despite the court’s construction requiring the claims to possess both “different thickness” and “different composition,” the expert only addressed the “different thickness” element. *Id.* at *8. As a result, the court excluded his testimony as “irrelevant” and “confusing” to a jury because the expert’s analysis vitiated the “different composition” claim element.⁸ *Id.* at *8-9.

Similar to *Minerva*, Dr. Luedtke ignores the Court’s construction that regardless of the order of steps e) and f), **Compound 4** with its *specifically claimed chemical structure* is a required claim element. D.I. 248 at 36 n.7, 37-38. Dr. Luedtke fails [REDACTED]

[REDACTED]

[REDACTED] Instead, he opines [REDACTED] contrary to the

⁸ The court further noted that the essential effect of granting the motion to exclude was that (as here) the expert would “not be allowed to testify that [the defendant’s] product infringes the relevant claims of [the asserted] patent based on the doctrine of equivalents.” *Id.* at *9.

[REDACTED]

Court's claim construction. Ex. 28, ¶31 (" [REDACTED]

[REDACTED]"); *id.*, ¶32 ([REDACTED]

[REDACTED] Ex. 34, 99:24-100:5.

In process patent claims that "recite a method for preparing a specifically named compound by combining another specifically depicted compound with a third specific compound" where "[e]ach of these compounds is expressly named, . . . an infringement analysis must not take lightly the specific recitation of these materials." *Mylan Inst.*, 857 F.3d at 869-70 (holding that the district "court's equivalents analysis was deficient in its [function, way, result] analysis" where it "failed to consider whether the key reagent in the process, manganese dioxide, was *substantially different from* the claimed reagent, silver oxide") (emphasis in original). Yet, Dr. Luedtke's DOE opinions do just that. Dr. Luedtke's DOE opinions violate the all elements rule and should be excluded.

2. Dr. Luedtke's Hypothetical Claims Analysis Is Legally Erroneous

Dr. Luedtke's use of hypothetical claims to evaluate DOE infringement is legally improper. *See* Ex. 28, ¶¶9-10. Whether an element of the accused process is equivalent to a claim element is evaluated using either the function, way, result or the insubstantial difference tests. *Mylan Inst.*, 857 F.3d at 866. The "hypothetical claim" analysis is different. It assesses whether the patentee has met its "burden to prove that it is *entitled to the range of equivalents it seeks*" by proving that the hypothetical claim that includes the alleged equivalent "*is patentable over the prior art.*" *TQ Delta, LLC v. DISH Network Corp.*, C.A. No. 15-614-RGA, D.I. 395, at *4 (D. Del. Feb. 2, 2022) (Ex. 62). Hypothetical claims are not used to show equivalence, [REDACTED]

[REDACTED] *E.g.*, Ex. 27, ¶¶139 [REDACTED]

[REDACTED]
[REDACTED]), 163 [REDACTED]
[REDACTED]). This is legal error.

Hypothetical claims cannot be used to rewrite asserted claims to overgeneralize and omit structural limitations in a DOE analysis. In *DeMarini Sports, Inc. v. Worth, Inc.*, the court rejected the patentee’s presentation of a “hypothetical claim allegedly showing that each limitation [was] met by a corresponding reversed-parts complement in” the accused device, calling it “linguistic chicanery.” 239 F.3d 1314, 1333-34 (Fed. Cir. 2001). In fact, the Federal Circuit explained that the patentee’s “hypothetical claim emphatically shows that this is not a case of a mere reciprocal change of two interacting elements, . . . , but involves a clear difference between the structure of the alleged infringing product and the invention as it has been defined by the limitations of the claims, as drafted.” *Id.* at 1334.

Similar to *DeMarini*, Dr. Luedtke’s hypothetical claim analyses [REDACTED]
[REDACTED]
[REDACTED] Ex. 27, ¶189. This analysis is legally wrong. A DOE analysis requires specific comparisons to the specific claim element, [REDACTED] not generalized references to “intermediates,” “oligomers,” and/or “derivatives” to argue equivalency.

3. Dr. Luedtke’s Legally Erroneous Opinions Apply to All of the ’322 Patent’s Asserted Claims

Because Dr. Luedtke’s DOE analyses apply to limitations in both independent claims of the ’322 Patent, these errors pervade his opinions regarding infringement of the ’322 Patent’s asserted dependent claims (i.e., claims 2-4 and 7-9) as well. Axiomatically, if an independent claim is not infringed, its dependent claims cannot be infringed either, as dependent claims contain all limitations of the independent claim. *Hutchins v. Zoll Med. Corp.*, 492 F.3d 1377, 1382 (Fed. Cir. 2007) (affirming summary judgment of noninfringement of all independent and dependent

claims based on a claim term present in all independent claims). As such, all Dr. Luedtke's opinions regarding infringement of the '322 Patent asserted claims—both of his expert reports in their entirety—should be excluded because they all involve use of legally incorrect standards and are therefore unhelpful to a factfinder.

D. Conclusion

Sarepta respectfully moves for the exclusion of Dr. Luedtke's DOE opinions and testimony.

VIII. CONCLUSION

For the forgoing reasons, Sarepta and UWA respectfully request the Court to exclude opinions and testimony of NS's experts discussed herein and specified in the accompanying motions.

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December 11, 2023

CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 11, 2023, upon the following in the manner indicated:

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